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Qiagen and Myriad Genetics design oncology test to analyse homologous recombination deficiency

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Next-generation-sequencing-based homologous recombination deficiency (HRD) assay



German firm Qiagen and US-based Myriad Genetics will develop a globally distributable kit-based test for analysing Homologous Recombination Deficiency (HRD) status. This next-generation sequencing (NGS) test aims to support research into personalised medicine in multiple solid tumour types, including ovarian cancer and is expected to enhance decentralised testing capacities once a regulated product is developed with pharmaceutical partners. The project builds on the recently announced master collaboration agreement between the two companies.

The test will be based on Qiagen's QIAseq xHYB technology, Qiagen Digital Insight solutions, which creates a sample to insight HRD solutions, and Myriad's proprietary US FDA-approved MyChoice CDx, a single-site PMA-approved centralised testing service for analysing HRD in certain tumours.

MyChoice CDx assesses the HRD status by examining a tumor's DNA repair capabilities, particularly focusing on*BRCA1* and *BRCA2* gene mutations and calculating a Genome Instability Score (GIS). The GIS aids in pinpointing ovarian cancer patients who are most likely to benefit from targeted treatments, such as LYNPARZA (olaparib) by AstraZeneca.

The MyChoice CDx assay can identify 34% more tumors with HRD using the GIS score compared to other methods only using percent loss of heterozygosity (%LOH). Given that approximately 48% of ovarian cancer tumors exhibit HRD, often due to specific mutations within the tumour, expanding access to this assay is vital for advancing personalised medicine and ensuring that patients receive the most appropriate treatments.

Qiagen will manage the development and distribution of the kit-based HRD test outside of the United States. The IP license grants Qiagen the capability to collaborate with pharmaceutical partners to create an IVD-validated test, intended for use as a companion diagnostic outside of the United States. The combined regulatory expertise of Qiagen and Myriad enables seamless compliance and integration in clinical and companion diagnostic applications.